

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : George Jackowski et al
INVENTION : INTER ALPHA TRYPSIN INHIBITOR
BIOPOLYMER MARKERS INDICATIVE OF
INSULIN RESISTANCE
SERIAL NUMBER : 09/991,795
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EXAMINER : Davis, Deborah A.
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Commissioner for Patents
P.O. Box 1450
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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent authorized to represent the inventor's and assignee in the application entitled "**Inter Alpha Trypsin Inhibitor Biopolymer Markers Indicative of Insulin Resistance**", having U.S. Application Serial No. 09/991,795, filed November 23, 2001.

2. In the Office Action mailed on June 15, 2007, Claim 1, was rejected under 35 U.S.C. §101, because the claimed invention allegedly is not supported by either a specific, credible or well

established utility, and 35 U.S.C. §112, first paragraph because, since the claimed invention is not supported by either a specific, substantial, asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention.

Specifically, the Examiner notes Applicant's claim that the identification of bands 2 and 3 in Figure 1 of the drawings are indicative of SEQ ID NO:1 and based on the differential expression of the bands between samples from normal and disease patients are indicative to a link to at least one disease. However, the Examiner asserts that: in Figure 1 of the drawings band 3 is not evident in Diabetes type I and one disease sample of Insulin Resistance; Figure 1 of the instant drawings reveal that band 3 is evident in one disease sample of Insulin Resistance and two normal samples; Band 2 in Figure 1 of the drawings is not evident in any normal or disease samples. The Examiner concludes that the differential expression of SEQ ID NO: 1 is not evident and the data results are ambiguous. The Examiner maintains that the correlation with respect to a link to insulin resistance is not exemplified or disclosed in the specification in a way that one of ordinary skill in the art could distinguish the differential expression in an insulin resistance subject versus that of a normal subject. The Examiner further asserts one of ordinary skill in the art would not be

able to distinguish a credible and specific or well establish utility that SEQ ID NO: 1 is linked to insulin resistance, and as a result, the specification does not identify a substantial, credible or well-established utility for sequence consisting of SEQ ID NO: 1.

3. Applicants submit that Figure 1, as originally filed, supports Applicants' finding of differential expression of SEQ ID NO:1 between disease state and normal patients. Figure 1, Band 2 corresponds to disease specific marker inter alpha trypsin inhibitor having molecular weight of about 1582 daltons and SEQ ID NO:2 (See Figure 2). Band 2 also corresponds to disease specific marker inter alpha trypsin inhibitor having molecular weight of about 1337 and SEQ ID NO:3(See Figure 4)daltons and SEQ ID NO:2 (See Figure 2). Figure 1 shows Band 2 expression in both normal and diseased state patients (Insulin Resistance and Diabetes I/II). Band intensity corresponding to the normal patients is higher when compared to the band intensity corresponding to disease patients.

4. Figure 1 shows Band 3 expression in diseased state patients (Insulin Resistance and Diabetes I/II), but not in samples form normal patients. Band 3 corresponds to disease specific marker inter alpha trypsin inhibitor having molecular

weight of about 1811 daltons and SEQ ID NO:1 (See Figure 3). Thus, the claimed SEQ ID NO:1 is differentially expressed in insulin resistance versus normal.

5. In order to further illustrate this point, Applicants provide the attached figure entitled "HiQ 1-(Elution) Insulin Resistance vs. Normal" which represents Figure 1 as originally filed. The attached figure was produced by scanning the original photograph of the gel. Expression of Band #2 is greater in samples obtained from normal patients (lanes 7-9) as compared to insulin resistance and Type I/II diabetes patients (lanes 2-6). Expression of Band 3 is shown in samples obtained from insulin resistance and Type I/II diabetes patients (lanes 2-6); no expression is seen in lanes corresponding to those samples obtained from patients determined to be normal with regard to insulin resistance/Type I/II diabetes (lanes 7-9). No new matter has been added; this figure is simply a clearer copy of Figure 1 as originally filed and is provided to clarify the presence and differential expression of the claimed biopolymer marker SEQ ID NO:1. The gel shown in the figure does not represent new experimentation; the figure shows a clearer image of the original gel made at the time that the experiments described in the instant specification were first carried out.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

Date

11/13/2007

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HiQ 1-(Elution) Insulin Resistance vs. Normal

